**Sim, Hughes, Ashton & McKay LLP**
*Barristers & Solicitors*

**Sim & McBurney**
*Patent & Trade Mark Agents*

6th Floor, 330 University Avenue
Toronto, Ontario, Canada M5G 1R7

**Tel. (416) 595-1155 • Fax (416) 595-1163**



**DATE: August 12, 2002**

**Application No.:** 08/286,189 **Our Ref:** 1038-384 MIS:jb

| TO: | FAX # | PHONE # |
|---|---|---|
| Examiner: Jeffrey S. Parkin<br>Group/Art Unit: 1648<br>US Patent Office | (703) 308-4242 | (703) 308-2227 |



Total Number of Pages (Including This Page): 12

**FROM:** Michael I. Stewart / 239

**COMMENTS:**

| CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8) Applicant(s): Sonia E. Sanhueza | | | Docket No. 1038-384 MIS:jb |
|---|---|---|---|
| Serial No 08/286,189 | Filing Date August 5, 1994 | Examiner Jeffrey S. Parkin | Group Art Unit 1648 |

Invention INACTIVATED RESPIRATORY SYNCYTIAL VIRAL VACCINES



I hereby certify that this Reply Brief
*(Identify type of correspondence)*
is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. (703) 308-4242
on August 12, 2002
*(Date)*

Michael I. Stewart (Reg. No. 24,973)
*(Typed or Printed Name of Person Signing Certificate)*

*(Signature)*

**Note: Each paper must have its own certificate of mailing.**

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)
Approved for use through 10/31/2002 OMB 0651-0031
Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE



# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Application | 08/286,189 |
| Filing Date | August 5, 1994 |
| First Named | Sonia E. Saulnier |
| Group Art Unit | 1648 |
| Examiner Name | Jeffrey S. Parkin |
| Total Number of Pages in This Submission: 10 | Attorney Docket Number: 1038-384 MIS |

## ENCLOSURES *(check all that apply)*

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) *(please identify below)*.

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|---|---|
| Firm or Individual name | Michael I. Stewart (Reg. No. 24,973) |
| Signature | |
| Date | August 12, 2002 |

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date

| | | | |
|---|---|---|---|
| Typed or printed name | | | |
| Signature | | Date | |

#36 Reply Brief 8/13/02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| Applicant | : | 08/286,189 |
| Appl'n. No. | : | Sonia E. Sanhueza |
| Filed | : | August 5, 1994 |
| Title | : | INACTIVATED RESPIRATORY SYNCYTIAL VIRAL VACCINES |
| Grp./A.U. | : | 1648 |
| Examiner | : | Jeffrey S. Parkin |
| Docket No. | : | 1038-384 MIS:jb |
| Date | : | August 12, 2002 |

**BY FACSIMILE**

The Commissioner of Patents
and Trademarks,
Box AF
Washington, D.C. 20231,
U.S.A.

**REPLY BRIEF**
**(Response Under 37 CFR 1.116 - Expedited Procedure)**

Dear Sir:

This Reply Brief is submitted in triplicate in response to the Examiner's Answer dated June 10, 2002 and to the Advisory Action of the same date.

In the Advisory Action, the Examiner indicated that the Declaration of Gregory A. Prince had not been considered on the basis of lack of timely submission and the absence of good and sufficient reasons why the Declaration had not been earlier presented.

An issue in this appeal is the extent to which the cotton rat is an art-recognized model of vaccine efficacy in humans. It is the foundation of the Examiner's argument that the pending claims are rejected under 35 USC 112, first paragraph, as lacking an enabling disclosure, that the cotton rat is not such a model.

Applicants had previously provided attorney argument, backed by reference to the literature, in support of their assertion that the cotton rat is an art-recognized model, in the reasonable belief that such argument would be persuasive

without further proof. When such argument was rejected, it was considered that a Declaration by a recognized expect in the field (see the CV attached to the Declaration), namely Professor Gregory A. Prince, would assist the Board in realizing the correctness of the applicants argument and that the appealed claims are fully enabled and fully comply with 35 USC 112, first paragraph.

The Declaration was not submitted earlier, since it was not considered necessary until the receipt of the Examiner's Final Rejection that such a Declaration would be necessary.

In addition, the Examiner specifically invited applicants to submit further evidence, stating in the Final Action:

> "Applicants are advised that the presentation of more appropriate publication or other evidence providing reproducible data derived from the cotton rat model might obviate the rejection." (emphasis added)

As pointed out in the Appeal Brief, the Prince Declaration was submitted specifically in response to this Invitation.

It is submitted that the Declaration of Gregory A. Prince should be entered and considered in this Appeal.

As to the Examiner's indications of the uncertainties in the art, in the Prince Declaration, it is pointed out that, on the strength of cotton rat data, the NIH funded a clinical trial of RSV prophylaxis in high risk infants using immunoglobulin (Prince, para. 4.2). This trial confirmed what the cotton rat had shown that immunoglobulin reduced viral titers (Prince, para. 4.3).

As set forth in the Appeal Brief, applicants determined that, if respiratory syncytial virus is first purified and then inactivated using β-propiolactone, ascorbic acid or octyl glycopyranoside, then a safe and effective vaccine preparation can be obtained which, in particular, elicits a protective immune response without causing enhanced pulmonary pathology.

Applicants present independent claim 1 to the vaccine, independent claims 5, 12 and 14 directed to the method of preparation ad independent claim 15 to a method of immunizing.

With respect to the product claims, it is noted that the vaccine not only may be used in the method of claim 15, but also may be used in diagnostic procedures (see original clams 17 to 19; Application No. 08/472,174). It is submitted that the product claims are fully enabled on this basis, irrespective of the cotton rat model issue.

With respect to the method claims, it is submitted that the method steps defined are fully described and exemplified in the disclosure. It is submitted that the method claims are fully enabled on this basis, irrespective of the cotton rat model issue.

Respectfully submitted,

Michael I. Stewart
Reg. No. 24,973

Toronto, Ontario, Canada,
(416) 595-1155
FAX No. (416) 595-1163

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| Applicant | : | 08/286,189 |
| Appl'n. No. | : | Sonia E. Sanhueza |
| Filed | : | August 5, 1994 |
| Title | : | INACTIVATED RESPIRATORY SYNCYTIAL VIRAL VACCINES |
| Grp./A.U. | : | 1648 |
| Examiner | : | Jeffrey S. Parkin |
| Docket No. | : | 1038-384 MIS:jb |
| Date | : | August 12, 2002 |

**BY FACSIMILE**

The Commissioner of Patents
and Trademarks,
Box AF
Washington, D.C. 20231,
U.S.A.

**REPLY BRIEF**
**(Response Under 37 CFR 1.116 - Expedited Procedure)**

Dear Sir:

This Reply Brief is submitted in triplicate in response to the Examiner's Answer dated June 10, 2002 and to the Advisory Action of the same date.

In the Advisory Action, the Examiner indicated that the Declaration of Gregory A. Prince had not been considered on the basis of lack of timely submission and the absence of good and sufficient reasons why the Declaration had not been earlier presented.

An issue in this appeal is the extent to which the cotton rat is an art-recognized model of vaccine efficacy in humans. It is the foundation of the Examiner's argument that the pending claims are rejected under 35 USC 112, first paragraph, as lacking an enabling disclosure, that the cotton rat is not such a model.

Applicants had previously provided attorney argument, backed by reference to the literature, in support of their assertion that the cotton rat is an art-recognized model, in the reasonable belief that such argument would be persuasive

without further proof. When such argument was rejected, it was considered that a Declaration by a recognized expect in the field (see the CV attached to the Declaration), namely Professor Gregory A. Prince, would assist the Board in realizing the correctness of the applicants argument and that the appealed claims are fully enabled and fully comply with 35 USC 112, first paragraph.

The Declaration was not submitted earlier, since it was not considered necessary until the receipt of the Examiner's Final Rejection that such a Declaration would be necessary.

In addition, the Examiner specifically invited applicants to submit further evidence, stating in the Final Action:

> "Applicants are advised that the presentation of more appropriate publication or other evidence providing reproducible data derived from the cotton rat model might obviate the rejection." (emphasis added)

As pointed out in the Appeal Brief, the Prince Declaration was submitted specifically in response to this Invitation.

It is submitted that the Declaration of Gregory A. Prince should be entered and considered in this Appeal.

As to the Examiner's indications of the uncertainties in the art, in the Prince Declaration, it is pointed out that, on the strength of cotton rat data, the NIH funded a clinical trial of RSV prophylaxis in high risk infants using immunoglobulin (Prince, para. 4.2). This trial confirmed what the cotton rat had shown that immunoglobulin reduced viral titers (Prince, para. 4.3).

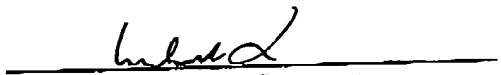
As set forth in the Appeal Brief, applicants determined that, if respiratory syncytial virus is first purified and then inactivated using β-propiolactone, ascorbic acid or octyl glycopyranoside, then a safe and effective vaccine preparation can be obtained which, in particular, elicits a protective immune response without causing enhanced pulmonary pathology.

Applicants present independent claim 1 to the vaccine, independent claims 5, 12 and 14 directed to the method of preparation ad independent claim 15 to a method of immunizing.

With respect to the product claims, it is noted that the vaccine not only may be used in the method of claim 15, but also may be used in diagnostic procedures (see original clams 17 to 19; Application No. 08/472,174). It is submitted that the product claims are fully enabled on this basis, irrespective of the cotton rat model issue.

With respect to the method claims, it is submitted that the method steps defined are fully described and exemplified in the disclosure. It is submitted that the method claims are fully enabled on this basis, irrespective of the cotton rat model issue.

Respectfully submitted,



Michael I. Stewart
Reg. No. 24,973

Toronto, Ontario, Canada,
(416) 595-1155
FAX No. (416) 595-1163